

REMARKS

Entry of the above amendment and reconsideration and withdrawal of the rejection of claims 47-64 and 66-85 is respectfully requested. Support for the amendment to Claim 47 may be found in the specification at page 7, lines 16-20.

1. Claims 47-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. Appln. Pubn. No. 2002/0160042 (hereinafter referred to as "Petereit") in view of U.S. Pat. Appln. Pubn. No. 2003/0068369 (hereinafter referred to as "McAllister '369").

The Final Office Action dated February 3, 2011 states that Petereit teaches a process for producing moldings by injection-molding and injection-molded capsules made thereby, which comprise methacrylate copolymers composed of 50% to 70% by weight of methyl acrylate, 10 to 30% by weight of methyl methacrylate, and 5% to 15% by weight of methacrylic acid. The Office Action states that Petereit does not teach the instantly claimed amount of surfactant (of less than 2% as in claim 56); does not teach the instantly claimed amount of the lubricant stearyl alcohol (from about 10 to about 15%); does not teach absorption enhancers and does not teach a blend of hydroxypropyl cellulose polymers having a differing molecular weight. The Office Action states that McAllister ('369) teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the assembled dosage form by a weld between parts of the assembled dosage form. The Office Action states that "blends of hydroxypropyl cellulose polymers having different molecular weight are disclosed at p. 12, ¶ 0150 and include KLUCEL. Suitable amounts of dissolution modifying agents (i.e., disintegrants) are about 10% to 40% as well as 10% to 70% for swellable solids such as hydroxypropylcellulose (p. 12, ¶ 0152). In the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a prima facie case of obviousness exists." The Office Action states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the specific ranges/amounts of surfactant and lubricant, the absorption enhancers and blends of hydroxypropyl cellulose polymers as taught by McAllister ('369) within the formulations of Petereit.

The Advisory Action states that Applicants' argument in the April 4, 2011 response contradicts that which is instantly recited, namely that ingredient (i) is a copolymer of Eudragit RS, Eudragit RL, or a combination of both, wherein said copolymer ranges from 10-80% w/w. The Advisory Action further states that regardless of the composition of ingredient (i), its presence does not begin at 20% w/w as asserted and that it further remains that optimization of the ranges of Eudragit under the guidance of the reference would have been well within the purview of the ordinarily skilled artisan."

In response, Applicants have amended the range of ingredient (i) in Claim 47 to reflect 20-50% w/w. Applicants submit that this rejection is now moot in light of the amendment to claim 47. Applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. §103(a) rejection of claims 47-64 and 66-87 over Petereit in view of McAllister '369.

2. Claims 47-64, 69-77, 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit in view of U.S. Pat. Appln. Pubn. No. 2003/0049311 (hereinafter referred to as "McAllister '311").

The Office Action states that Petereit teaches a process for producing moldings by injection-molding and injection-molded capsules made thereby, which comprise methacrylate copolymers composed of 50% to 70% by weight of methyl acrylate, 10 to 30% by weight of methyl methacrylate, and 5% to 15% by weight of methacrylic acid. The Office Action states that Petereit does not teach the instantly claimed amount of surfactant (of less than 2% as in claim 56); does not teach the instantly claimed amount of the lubricant stearyl alcohol (from about 10 to about 15%); does not teach absorption enhancers and does not teach a blend of hydroxypropyl cellulose polymers having a differing molecular weight. The Office Action states that McAllister ('311) teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the assembled dosage form by a weld between parts of the assembled dosage form. The Office Action states that the "dissolution modifying agents can comprise hydroxypropylmethyl cellulose and other hydroxyalkyl cellulose derivatives p. 11, ¶ 0146-0147. Suitable amounts of dissolution modifying agents (i.e. disintegrants, swellable solids) are from 2.5% to 70% w/w (p. 11, ¶ 0146). In this case where the claimed ranges "overlap

or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)." The Office Action states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the specific ranges/amounts of surfactant and lubricant, the absorption enhancers and blends of hydroxypropyl cellulose polymers as taught by McAllister ('311) within the formulations of Petereit. The Advisory Action states that the Examiner respectfully maintains this rejection for the same reasons made under the rejection for claims 47-85 and for these reasons, Applicants' arguments are found unpersuasive.

Applicants respectfully traverse the rejection. None of the cited references teaches a copolymer of Ammonio methacrylate Copolymer Type A (Eudragit RL) or Ammonio methacrylate Copolymer Type B (Eudragit RS) or a combination thereof present in an amount of about 20 to about 50% w/w. Applicants further submit that this rejection is also moot in light of the amendment to claim 47.

Based on the arguments above, Applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. §103(a) rejection of claims 47-64, 69-77, 82 and 83 over Petereit in view of McAllister '311.

CONCLUSION

Applicant respectfully requests reconsideration of the rejection of the above-mentioned claims and request an early and favorable allowance.

Respectfully submitted,

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